UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,837	09/17/2003	James T. Perkins	P03320	4911

23702 7590 09/18/2008

Bausch & Lomb Incorporated
One Bausch & Lomb Place
Rochester, NY 14604-2701

EXAMINER	
STIGELL, THEODORE J	
ART UNIT	PAPER NUMBER
3763	
MAIL DATE	DELIVERY MODE
09/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JAMES T. PERKINS and PAUL J. FERREIRA

Appeal 2008-4767
Application 10/664,837
Technology Center 3700

Decided: September 18, 2008

Before ERIC GRIMES, LORA M. GREEN, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1, 2, 5, 6, 9, and 10. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a phacoemulsification cannula. Claim 1 is representative of the claims on appeal, and read as follows:

1. A phacoemulsification cannula comprising:
a threaded hub for engagement with a phacoemulsification surgical instrument;
an elongated phacoemulsification needle having a proximal end attached to the hub and a distal end; and
the phacoemulsification needle having a first and second inner diameter wherein the first inner diameter is larger than the second inner diameter and wherein a transition from the first inner diameter to the second inner diameter is closer to the proximal end than to the distal end and wherein the first inner diameter extends from the distal end toward the proximal end, and wherein ultrasonic energy is transferred from the surgical instrument to the needle during surgery.

The Examiner relies on the following references:

Zadno-Azizi	US 5,997,562	Dec. 7, 1999
Eliasen	US 6,332, 874 B1	Dec. 25, 2001

We affirm.

ISSUE

The Examiner contends that the appealed claims are obvious over the combination of Zadno-Azizi and Eliasen.

Appellants contend that the combination does not render the claimed phacoemulsification cannula obvious, and that the Examiner erred in giving little or no weight to the recitation of the functional language "phacoemulsification" in the claims.

Thus, the issue on Appeal is: Whether the Examiner has established a prima facie case that the phacoemulsification cannula of claim 1 would have

been obvious over the combination of Zadno-Azizi and Eliasen, or has the Examiner erred in giving little or no weight to the recitation of the functional language "phacoemulsification" in claim 1?

FINDINGS OF FACT

FF1 The invention is drawn to "a phaco needle having at least two (2) distinct inner diameters." (Spec. ¶ 1.)

FF2 Figure 4 of the instant disclosure is reproduced below.

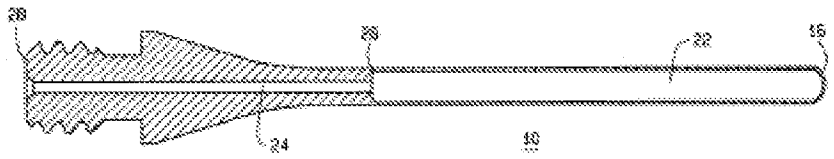


FIG. 4

Figure 4 shows a cut away of a phaco needle (Spec. ¶ 9).

> [The] needle 10 including a first bore or inner diameter 22 extending from the distal end 16 toward the proximal end 28, a second bore or inner diameter 24 within the cannula 10 extends from the proximal end 28 to the first bore 22. As can be seen, the second bore 24 has a smaller diameter than the first bore. It is also preferable that second bore 24 is of sufficient length to provide a desired pressure drop during use across the length of the second bore 24. This pressure drop enables the user to use higher vacuum levels and still maintain relatively low flow rates. Also, it is preferred that the intersection or transition 26 of the first and second bores 22 and 24 is nearer the proximal end 28 than to the distal end 16.

(Spec. ¶ 17.)

FF3 The Examiner rejects claims 1, 2, 5, 6, 9, and 10 under 35 U.S.C. § 103(a) as being obvious over the combination of Zadno-Azizi and Eliasen.

FF4 The Examiner, citing Figure 1 of Zadno-Azizi, finds that Zadno-Azizi discloses a cannula comprising a hub "that is capable of being engaged with a phacoemulsification surgical instrument." (Ans. 4.)

FF5 The Examiner finds further that the cannula of Zadno-Azizi also comprises an elongated needle having a proximal end attached to the hub and a distal end, "wherein the needle has a first inner diameter/bore (14a) extending from the distal end toward the proximal end that is larger than the second inner diameter/bore (14b) and wherein a transition region (21) from the first diameter to the second is located closer to the proximal end than the distal end, and wherein the cannula is capable of transferring some ultrasonic energy at least a small distance from a surgical instrument." (Ans. 4-5.)

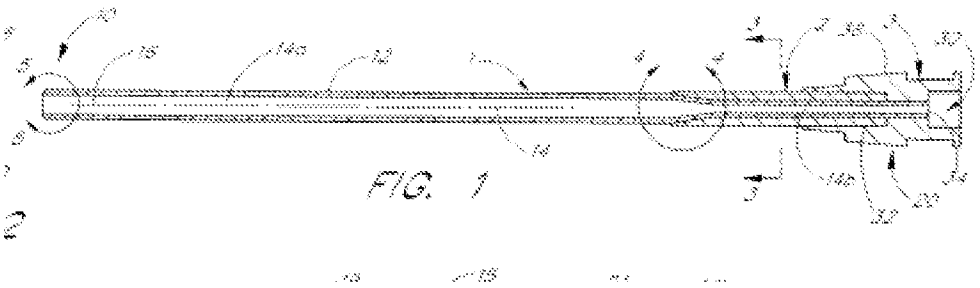
FF6 The Examiner notes that Zadno-Azizi teaches a luer lock rather than a threaded hub, but also teaches that any connector may be used (Ans. 5). Eliasen is relied upon for teaching that the use of a threaded connection on catheter/tubular systems is known in the art, and thus concludes that "[i]t would have been obvious to one of ordinary skill in the tubular devices in the medical arts to modify or substitute the luer connector of Zadno-Azizi . . . with a luer connector which is threaded as taught by Eliasen . . . in order to provide a secure connection between elements." (*Id.*)

FF7 Zadno-Azizi teaches a protective sheath assembly that "comprises a protective sheath having a proximal end, a distal end, and an elongated

hollow body defining a lumen along the longitudinal axis of the protective sheath." (Zadno-Azizi, col. 2, ll. 59-62.)

FF8 Zadno-Azizi teaches "[a] connecting member or hub is located at the proximal end of the sheath" (*id.* at col. 3, ll. 66-67).

FF9 Figure 1 of Zadno-Azizi is reproduced below.



FF10 Figure 1 of Zadno-Azizi shows a cross-sectional view of the protective sheath assembly (*id.* at col. 5, ll. 65-67). The assembly has a protective sheath 1, and a female luer lock 3 at proximal end 20 (*id.* at col. 6, ll. 37-49).

FF11 Zadno-Azizi teaches that "[t]he lumen **14** can be . . . divided into two portions, the proximal portion **14***b* with a smaller dimension starting from the proximal end **20** and the distal end **14***a* with the longer dimension starting from the distal end **10**." (*Id.* at col. 6, ll. 55-61.) The protective sheath assembly is not limited to any particular dimension (*id.* at col. 7, ll. 66-67).

FF12 The sheath may be made from various polymer materials, such as PEBAX, PE, PEEK, FEP, PTFE, polyimide (Nylon), polycarbonate, etc., and may be produced as a single unit (*id.* at col. 8, ll. 58-67).

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 1739. Moreover, an "[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982).

"A patent applicant is free to recite features of an apparatus either structurally or functionally." *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997). However, defining features functionally carries a risk, because when "'the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.'" *Id.* (quoting *In*

re Swinehart, 439 F.2d 210, 213 (CCPA 1971); *see also Leggett & Platt, Inc. v. VUTEk, Inc.*, 537 F.3d 1349 (Fed. Cir. 2008).

Moreover, during prosecution before the Office, claims are to be given their broadest reasonable interpretation consistent with the Specification as it would be interpreted by one of ordinary skill in the art. *In re American Academy Of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). "An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process." *In re Zletz*, 893 F.2d 319, 322 (Fed. Cir. 1989). Moreover, it is during prosecution that applicants have "the opportunity to amend the claims to obtain more precise claim coverage." *American Academy*, 367 F.3d at 1364.

ANALYSIS

As Appellants do not argue the claims separately, we focus our analysis on independent claim 1, and claims 2, 5, 6, 9, and 10 stand or fall with that claim. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 1 is a product claim, and is drawn to a phacoemulsification cannula, comprising:

1) a threaded hub;

2) an elongated needle having a proximal end attached to the hub and a distal end;

3) the needle having a first and second inner diameter wherein the first inner diameter is larger than the second inner diameter and wherein a

transition from the first inner diameter to the second inner diameter is closer to the proximal end than to the distal end and wherein the first inner diameter extends from the distal end toward the proximal end.

The recitation that the threaded hub is "for engagement with a phacoemulsification surgical instrument" is a statement of intended use, and not a patentable limitation. In addition, in giving the claims their broadest reasonable interpretation, we conclude that all that is required by the recitation that the "ultrasonic energy is transferred from the surgical instrument to the needle during surgery" is that the cannula be capable of transferring ultrasonic energy to the needle. Given that interpretation, we conclude that the Examiner has set forth a prima facie case of obviousness, and we thus turn to Appellants' arguments in rebuttal.

Appellants argue that "[s]ince the cited prior art is not concerned with ultrasonic energy transmission and does not mention ultrasound anywhere in the patent, it is improper for the Examiner to assume the sheath has such capabilities." (App. Br.[1] 4-5.) Zadno-Azizi, Appellants assert, discloses a slip fit assembly of the sheath assembly's various parts, and ultrasonic energy would shake it apart, and even if it were made of one piece, as suggested by the reference, "it is not clear that ultrasonic energy could be effectively transmitted though such a sheath." (*Id.* at 5.) According to Appellants, "[p]hacoemulsification cannulas are typically quite rigid and almost always made from metallic materials such as titanium so that the ultrasonic energy is efficiently transmitted through the cannula and so that

---

[1] All references to the Appeal Brief (App. Br.) are to the Amended Appeal Brief dated July 13, 2007.

the cannula can withstand the significant forces applied to it as it breaks up a cataract in a patient's eye." (*Id.*) Appellants argue further that the "cited prior art indicates its total length is 3.6 inches (col. 8, line 3)," and that "[s]uch a long length would be very difficult, if not impossible, to use in such a . . . space as an eye." (Reply Br. 3.)

Appellants' arguments are not convincing. Claim 1 is drawn to a product, not a process, and the combination of Zadno-Azizi and Eliasen teaches all of the components of the claimed product. As Appellants note, Zadno-Azizi teaches that the assembly taught by the reference may be made as a single piece, and there is no evidence on the record that the assembly of Zadno-Azizi made as a single piece could not transmit ultrasonic energy. Note that arguments of counsel cannot take the place of evidence in the record. *In re Scarbrough*, 500 F.2d 560, 566 (CCPA 1974). As to Appellants' arguments that phacoemulsification cannulas are typically quite rigid and almost always made from metallic materials such as titanium, there is no evidence of that in the record, and more importantly, such a limitation does not appear in the claim. In addition, the assembly of Zadno-Azizi is not limited to any particular dimension, thus Appellants' argument that the cannula of Zadno-Azizi could not be used in the eye is unavailing, and again, Appellants are arguing process limitations, not product limitations.

Appellants argue further that the "prior art cited by the Examiner is not within the field of endeavor of the applicant and has improperly been cited against the pending claims." (App. Br. 6.) Citing *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992), Appellants further contend that the Examiner is engaged in improper hindsight in rejecting the claims (App. Br. 7).

Moreover, Appellants assert, the Supreme Court's decision in *KSR* does not obviate the above arguments, as the "present invention allows for greater transfer of ultrasonic displacement energy and operation at a higher vacuum rate with a lower flow rate than prior phacoemulsification needles. This advantage has nothing to do with the inserter sheath of Zadno-Azizi." (App. Br. 8.)

Appellants' argument that the cited prior art is not within Appellants' field of endeavor is not persuasive on the issue of obviousness, as claim 1 is drawn to a product, and Zadno-Azizi teaches all of the structural limitations of that product except for the use of a threaded hub, and Eliasen makes up that deficiency. Moreover, Appellants appear to be arguing unexpected results, but "[i]t is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice." *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984).

According to Appellants, the Examiner "has given little or no weight to the functional language of the claims that was added to distinguish the present claimed invention from the cited art," which "is in complete opposition to long-standing law." (App. Br. 10.) Appellants argue that "[i]ndependent claims 1, 5, and 9 have been amended to specifically refer to the needle and surgical instrument as a phacoemulsification needle and a phacoemulsification surgical instrument," which "clearly removes any similarity between the cited prior art and the claimed present invention." (*Id.*)

We acknowledge that Appellants are entitled to claim product limitations functionally. However, where, as here, there is reason to believe that the functional limitation of the ability to transmit ultrasonic energy that Appellants assert is critical for establishing the unobviousness of the claimed subject matter is, in fact, an inherent characteristic of the assembly of Zadno-Azizi, the Office possesses the authority to require Appellants to prove that the assembly of Zadno-Azizi does not possess that characteristic. As Appellants have not provided such evidence, the rejection is affirmed.

CONCLUSIONS OF LAW

Thus, we conclude that the Examiner has established a prima facie case that the phacoemulsification cannula of claim 1 is obvious over the combination of Zadno-Azizi and Eliasen, and thus has not erred in giving little or no weight to the recitation of the functional language "phacoemulsification" in claim 1. The rejection of claims 1, 2, 5, 6, 9, and 10 under 35 U.S.C. § 103(a) as being obvious over the combination of Zadno-Azizi and Eliasen is therefore affirmed.

TIME LIMITS

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

cdc

Bausch & Lomb Incorporated
One Bausch & Lomb Place
Rochester NY 14604-2701